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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,078	12/21/2000	Woodrow C. Monte	32166.00002	2298

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/747,078	MONTE, WOODROW C.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *10,12 and 42-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11, and 13-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the invention of species of enzymes, in Paper No. 6, submitted March 12, 2002 is acknowledged.

Again, Applicant's election with traverse of the invention of Group I, claims 1-24, in Paper No. 3 submitted December 6, 2001 is acknowledged in the previous Office Action mailed January 29, 2002. As discussed in the previous Office Action, the restriction is modified as to combine Group I and II into a single invention, new Group I, claims 1-41.

The traversal is on the ground(s) that it would not be an undue burden upon the Office to examine Group I (claims 1-41) drawn to a method for adding a heat-sensitive active material such as an enzyme or antibody to a composition; and new Group II (claims 42-46) drawn to a device and a tablet. This is not found persuasive. As discussed in the Restriction Requirements mailed November 6, 2001 and January 29, 2002, the inventions of new Groups I and II are seen to be separate and distinct inventions properly restricted from each other since they are related as process of use and product.

The requirement is still deemed proper and is therefore made FINAL.

Claims 42-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Therefore, claims 10 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The claims have been examined insofar as they read on the elected specie.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11, and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86

USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recite the broad recitation "a heat-sensitive active material" and the claim also recites "such as an enzyme" which is the narrower statement of the range/limitation.

The expression "a temperature capable of denaturing the active" in claims 1-2, 5,7, and 25 renders claims 1-9, 11, and 13-41 indefinite. The expression "a temperature capable of denaturing the active" is not defined by the claims. Therefore, the scope of claims is indefinite as to the temperature encompassed thereby.

The expression "slowly enough" in claims 1-2 is a relative term which renders claims 1-9, 11, and 13-41 indefinite. The expression "slowly enough" is not defined in the specification and claim. The scope of the claims is indefinite since the degree of the dissolving rate of the tablet is unclear.

The expression "a beneficial effect" in claims 1-2 renders claims 1-9, 11, and 13-24 indefinite. The expression "a beneficial effect" is not defined in the specification and claim. The scope of the claims is indefinite as what is considered to be "a beneficial effect".

The expressions "an active" in claim 2 and "another substance" in claim 25 render claims 3-9, 11, and 13-41 indefinite. The expressions "an active" in claim 2 and "another substance" are not defined in the specification and claim. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claim R jections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11, and 13-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (5,707,843, PTO-1449 submitted January 9, 2002) in view of Monte (5,578.336 and 5,424,299, PTO-1449 submitted January 9, 2002).

Monte discloses a method therein including steps: adding an enzyme or lactose-converting enzyme to a composition, heating the composition therein to a temperature at which the enzyme may be denatured, and packaging the enzyme composition, or cooling the enzyme composition. Monte also discloses the lactose enzyme composition therein is a food product such as a milk product. Moreover, Monte discloses that the lactose therein can be converted from 50% to 99% and that the composition has pH of 6.0 or less. See abstract, col.1 lines 21-39, col. 2. lines 7-10 and 18-49, col.5 lines 36-45, and claims 4-5.

Monte does not expressly disclose providing a tablet including the active, the tablet being coated and adding the tablet to the container in the instant claimed method for adding the particular heat-sensitive active material, enzyme. Monte does also not expressly disclose the coating may be sugar and the food may be an enteral food.

Monte (5,578.336) discloses that the coating of the enzyme candy composition therein is sugar or sugarless sweetener. See abstract and col.2 lines 65-67, and Examples.

Monte (5,424,299) discloses that the food containing enzyme composition therein is an enteral food. See abstract, col.1 lines 64-66, Examples and claims 1-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a tablet including the active, the tablet being coated and to add the tablet to the container in the instant claimed method for adding the particular heat-sensitive active material, enzyme, and to coat the tablet with sugar and prepare the particular food, an enteral food.

One having ordinary skill in the art at the time the invention was made would have been motivated to provide a tablet including the active, the tablet being coated and to add the tablet to the container in the instant claimed method for adding the particular heat-sensitive active material, enzyme, and to coat the tablet sugar and prepare the particular food, an enteral food, since these steps herein i.e., providing a tablet including the active, the tablet being coated and adding the tablet to the container, and coating the tablet with sugar and preparing the particular food, an enteral food, are considered well in the competence level of an ordinary skilled artisan in the art, involving merely routine skill in the art. Moreover, these steps are also considered to be conventional steps in pharmaceutical or food science. Further, adding the particular heat-sensitive active material, enzyme, into a composition, coating an enzyme candy composition with

sugar and preparing an enteral food containing enzyme composition are known in the art according to Monte.

Thus, the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. A. Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 30, 2002

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